REMARKS

Status of Claims:

New claims 29-33 are added. Thus, claims 1-33 are present for examination.

Claim Rejections:

Claims 1-4, 15-18, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Marggi (U.S. Patent Number 6,302,866).

Claims 1-3, 5-7, 10-17, 19-21, and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiasen (U.S. Patent Number 5,980,506).

Claims 1, 8, 9, 15, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (U.S. Patent Number 5,545,143).

With respect to claims 1-28, as amended, the rejections are respectfully traversed.

Independent claim 1, as amended, recites an infusion set, comprising:

> "a base for providing an infusion path, said base having a first surface that faces a skin surface of a user when said base is supported on said skin surface and when said infusion set is used to pass fluids to said user;
>
> a cannula connected to and extending away from the base;
>
> a connector removably attachable to the base; and
>
> a tubing affixed to the connector,
>
> wherein the connector is **rotatable** on the base, **to more than 5 degrees and limited to less than 360 degrees** around an axis that is **substantially perpendicular** to said first surface of said base, when the connector is removably attached to the base, and
>
> wherein a contiguous passage for passing fluids is formed from the tubing to the cannula when the connector is removably attached to the base." (Emphasis Added).

An infusion set including the above-quoted features has at least the advantages that: (i) a connector is **rotatable** on a base around an axis that is **substantially perpendicular** to a first surface of the base, where the first surface of the base faces a skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user; and (ii) the rotation of the connector on the base is **allowed** to **more than 5 degrees**, but is **limited** to **less than 360 degrees**. (Specification; paragraphs [0007], [0038]-[0040], [0046], and [0055]-[0058]).

Marggi neither discloses nor suggests an infusion set including the above-quoted features with a connector that is **rotatable** on a base to **more than 5 degrees**. The Examiner points to the cannula housing 2 and the needle holder 3 of the system of Marggi as disclosing a base and connector, respectively. Also, the Examiner states that, "[t]he connector **does not have a great capability to rotate** on the base but can **conceivably rotate a few degrees** in either direction if enough pressure is exerted on the handles of the connector". (Emphasis Added).

However, the needle holder 3 of Marggi is neither designed nor meant to be used as a rotatable connector. Indeed, Marggi states that, "[d]uring connection or assembly, the cannula housing and the needle holder are preferably automatically engaging with each other, in particular due to the needle holder being detachably **anchored** to the cannula housing." (Marggi; column 2, lines 20-25) (Emphasis Added). In particular, in the system of Marggi, a guide sleeve 7 has two elastic snap-on **fingers** 16 that **engage** with appropriate **guide shafts** 15 provided on either side of a cylindrical extension 6 in the cannula housing 2 when attaching the needle holder 3. (Marggi; FIG. 3; column 5, lines 39-50). Marggi further states that, the "snap-on fingers 16 are snapped out by their engaging tabs behind projections formed in the guide shafts 15 upon the connecting needle 4 having been completely inserted, thus **anchoring** the needle holder 3 at the cannula housing 2 by **gripping** behind the appropriate projections of the guide shafts." (Marggi; column 5, lines 47-54) (Emphasis Added).

Moreover, Marggi states that, "[w]hen attaching the needle holder 3, the underside 14 of the needle holder 3 slides along the curved upper side 13 of the cannula housing 2", and that,

"[t]he guide sleeve 7 is positioned **flush** with the cylindrical extension 6 for positioning the connecting needle 4". (Marggi; FIG. 4; column 5, line 66 to column 6, line 2). In the system of Marggi, with the snap-on fingers 16 **engaged** in the guide shafts 15, and the guide sleeve 7 positioned **flush** with the cylindrical extension 6, it is doubtful that any rotation of the needle-holder 3 with respect to the cannula housing 2 would be allowed. However, to further expedite prosecution of the present patent application, claim 1 has been amended to recite the limitation that the connector is rotatable on the base to **more than 5 degrees**. Marggi certainly does not teach such rotation of a connector, and if extreme pressure were applied to the system of Marggi as suggested by the Examiner, then the needle holder 3 would likely break-off, because the system of Marggi is not designed for rotation of the needle holder 3 around the cannula housing 2.

Similarly, Fischell neither discloses nor suggests an infusion set including the above-quoted features with a connector that is **rotatable** on a base to **more than 5 degrees**. The Examiner points to the main body 210 and the assembly 240 of the system of Fischell as disclosing a base and connector, respectively. Also, the Examiner states that, "[t]he connector (240) **does not have a great capability to rotate**, but can **conceivably rotate a few degrees** in either direction if enough pressure is applied." (Emphasis Added).

However, the assembly 240 of the system of Fischell is neither designed nor meant to be used as a rotatable connector. Instead, as illustrated in FIGs. 15 and 16 of Fischell, the assembly 240 has a three-pronged connector 241, where the three-pronged connector 241 has a central prong 244 that is used to help guide a plastic needle 245 into a slit 204 of a septum 205 of the main body 210. The connector 241 of the system of Fischell is also guided into the tapered entry holes 226 of the main body 210 by means of the tapered **locking** pins 246 located on the **outer two prongs** of the three pronged connector 241. (Fischell; FIGs. 15 and 16; column 12, lines 35-40).

Fischell states that, "when the connector 241 is positioned just above the main body 210 as shown in FIG. 15, a downward finger pressure can be used to push the **locking** pins 246 into

the tapered entry holes 226 as shown in FIGS. 15 and 16", and that, "[w]hen this is accomplished, the **lip** 225 of the cannula section 220 is **locked onto** the **mating lip** 247 of the **locking** pins 246." (Fischell; FIG. 16; column 12, lines 39-45) (Emphasis Added). In the system of Fischell, with the **lip** 225 of the cannula section 220 **locked onto** the **mating lip** 247 of the **locking** pins 246, it is doubtful that any rotation of the assembly 240 with respect to the main body 210 would be allowed. However, to further expedite prosecution of the present patent application, claim 1 has been amended to recite the limitation that the connector is rotatable on the base to **more than 5 degrees**. Fischell certainly does not teach such rotation of a connector, and if extreme pressure were applied to the system of Fischell as suggested by the Examiner, then the assembly 240 would likely break-off, because the system of Fischell is not designed for rotation of the assembly 240 around the main body 210.

With respect to Mathiasen, the Examiner points to the housing 1 and the base element 8 of the system of Mathiasen as disclosing a base, and to the connector 3 of the system of Mathiasen as disclosing a connector. The Examiner further states that, "[t]he connector (3) has limited rotation on the base element (8) that can be restricted by the base element (8)." However, independent claim 1 has now been amended to recite the limitation that, "the connector is **rotatable** on the base ... around an axis that is **substantially perpendicular** to said first surface of said base", where the first surface of the base faces a skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user.

Mathiasen neither discloses nor suggests an infusion set including the above-quoted features with a connector that is **rotatable** on a base around an axis that is **substantially perpendicular** to a first surface of the base, where the first surface of the base faces a skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user. Instead, in the system of Mathiasen, the housing 1 to which the connector 3 is connected **pivots** around an axis that is **parallel** to a surface of the base element 8 that faces a skin surface of a user when the infusion device of Mathiasen is used to deliver fluid to the user. (Mathiasen; FIG. 3; column 2, lines 3-8). Thus, Mathiasen does not allow for

rotating the connector 3 around an axis that is **substantially perpendicular** to a surface of the base element 8 that faces a skin surface of a user when the device of Mathiasen is used to deliver fluid to the user.

Therefore, independent claim 1, as amended, is neither disclosed nor suggested by the Marggi, Mathiasen, and Fischell references and, hence, is believed to be allowable. Because they depend from independent claim 1, dependent claims 2-9 and 26 are believed to be allowable for at least the same reasons that independent claim 1 is believed to be allowable.

In addition, dependent claim 26 recites the further distinction, "wherein the connector is rotatable on the base to **more than 10 degrees** and limited to less than 360 degrees around said axis." (Emphasis Added). It is clear that neither the system of Marggi nor the system of Fischell allow for a connector to be rotated on a base to **more than 10 degrees**. Therefore, dependent claim 26 is believed to be allowable for at least that additional reason.

Independent claim 10 recites a method for using an infusion set with features similar to features of an infusion set of independent claim 1. Therefore, independent claim 10 is believed to be allowable for at least the same reasons that independent claim 1 is believed to be allowable. Because they depend from independent claim 10, dependent claims 11-14 and 27 are believed to be allowable for at least the same reasons that independent claim 10 is believed to be allowable.

Independent claim 15 recites a subcutaneous infusion set with features similar to features of an infusion set of independent claim 1. Therefore, independent claim 15 is believed to be allowable for at least the same reasons that independent claim 1 is believed to be allowable. Because they depend from independent claim 15, dependent claims 16-23 and 28 are believed to be allowable for at least the same reasons that independent claim 15 is believed to be allowable.

Independent claim 24 recites an infusion set with features similar to features of an infusion set of independent claim 1. Therefore, independent claim 24 is believed to be allowable for at least the same reasons that independent claim 1 is believed to be allowable. Because it

depends from independent claim 24, dependent claim 25 is believed to be allowable for at least the same reasons that independent claim 24 is believed to be allowable.

Conclusion:

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

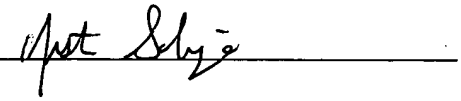
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date September 29, 2005

By 

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